Department of LABOR AND INDUSTRIES

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PROVIDER BULLETIN

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THIS ISSUE

Recent Formulary Coverage Decisions and Drug Updates

TO:

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Purpose

The purpose of this bulletin is to notify providers of the recent formulary coverage decisions pertaining to Actiq® and topical local anesthetics, EMLA® and Lidoderm®. These coverage decisions are applicable to both State Fund and Self-Insured claims and are currently in effect. Also included is a reminder that compound medications require prior authorization and that rules regarding the payment of opioids are also applied to Ultram® (WACs 296-20-03019 through 296-20-03023).

Formulary Coverage Decisions

ACTIQ (oral transmucosal fentanyl citrate)

Actiq®, an oral transmucosal fentanyl citrate lozenge on a stick, is indicated for the management of breakthrough cancer pain in patients with malignancies who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain.

In reviewing the pharmacokinetic profile and efficacy and safety data on Actiq®, the department is concerned that Actiq®'s onset of analgesia is similar to that of injectable morphine with maximal concentrations of routine doses reaching plasma levels that have been shown to depress respiratory response. The department also has safety concerns regarding Actiq®'s formulation, raspberry-flavor lozenge on a stick, on specific subpopulations (eg, children, the elderly). In addition, there have not been any randomized, controlled clinical trials published in peer-reviewed journals on Actiq® for the treatment of breakthrough non-cancer pain.

Because of a lack of FDA approval for treatment in non-cancer patients and the above concerns, the department will **not** cover Actiq® for the management of breakthrough non-cancer pain and considers its status to be non-formulary.

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EMLA (lidocaine 2.5% + prilocaine 2.5%) cream & LIDODERM (lidocaine 5%) patch

EMLA® is a eutectic mixture of lidocaine and prilocaine (1:1 by weight) that is indicated as a topical anesthetic for use on normal intact skin for local analgesia. Lidoderm® is a patch of 5% lidocaine and is indicated for the relief of pain associated with post-herpetic neuralgia.

The pharmacokinetic data on EMLA® cream demonstrated that, at normal dosing recommendations, the maximal plasma concentrations of lidocaine and prilocaine are approximately 1/20 and 1/36, respectively, of toxic levels. However, the application of EMLA® to broken skin or to an area of more than 2,000 cm^2 may result in higher plasma levels that could produce a systemic pharmacologic response in susceptible individuals. Similarly, the mean peak plasma concentration (128 ng/mL) of lidocaine from Lidoderm®, at maximum recommended doses, is well below the concentration (6 µg/mL) known to induce systemic toxicity. There is also no evidence of systemic accumulation with repeated dosing with Lidoderm® patch.

Currently, no randomized, placebo controlled clinical trials have been published on EMLA® or Lidoderm ®for the treatment of non-localized pain or neuropathic pain other than post-herpetic neuralgia. As such, the department will only cover EMLA® for treatment of localized pain and Lidoderm® for post-herpetic neuralgia, when it is a proper and necessary treatment for an injured worker. See Washington Administrative Code (WAC) 296-20-01002 for a complete definition of "proper and necessary" medical services.

Drug Updates

ULTRAM (tramadol)

Ultram® is a central acting analgesic medication. Its pharmacologic effect is due to the binding of both parent and metabolite, M1, to µ-opioid receptors as well as inhibiting the reuptake of norepinephrine and serotonin. As such, Ultram® is recognized as an opiate agonist by the American Hospital Formulary Service (AHFS) Pharmacologic—Therapeutic Classification. Although Ultram® is a non-scheduled opioid, there have been reports in the literature of abuse, dependence, and withdrawal associated with its use.

As a reminder, the department recognizes Ultram® as an opioid. Thus, payment for Ultram® will be subjected to the department's opioid rules and guidelines, regardless of the level for potential abuse or whether it has "pure" opiate agonist properties. See WACs 296-20-03019 through 296-20-03023 for payment of opioids to treat chronic, non-cancer pain.

COMPOUND MEDICATIONS

This is a reminder to providers that *all* compound medications require prior authorization from the department or self-insured employer (see the department's 2001 fee schedule, page 206) before the product can be compounded and dispensed to injured workers. Once authorization is given, it is not necessary to seek approval again until authorization expires. Currently, compound medications include, but are not limited to, antibiotic intravenous therapy, pain cocktail, total parenteral nutrition,

and non-commercially available topical preparations. Please contact the Provider Hotline (1-800-848-0811), the State Fund-Claim Managers or the self-insured employer for authorization.

Please note the current billing method for compound medications is by paper bill. Providers may order the Statement for Compound Prescription (F245-010-000) through the Provider Hotline or directly from:

Warehouse
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PO Box 44843
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